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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,178	08/28/2003	Jorg Breitenbach	7113US01	5951

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ROBERT DEBERARDINE
ABBOTT LABORATORIES
100 ABBOTT PARK ROAD
DEPT. 377/AP6A
ABBOTT PARK, IL 60064-6008

EXAMINER	
STITZEL, DAVID PAUL	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/650,178	BREITENBACH	
	Examiner	Art Unit	
	David P. Stitzel, Esq.	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

OFFICIAL ACTION

Restriction/Election

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-19 are drawn to a pharmaceutical composition in solid dosage form comprising: at least one HIV protease inhibitor; at least one pharmaceutically acceptable water-soluble polymer; at least one pharmaceutically acceptable surfactant; and at least one additive, as classified in class 424, subclass 464.

II. Claims 20 and 21 are drawn to a method of preparing said pharmaceutical composition in solid dosage form, as classified in class 514, subclass 370.

III. Claim 22 is drawn to a method of treating an HIV infection in a mammal comprising administering said pharmaceutical composition in solid dosage form to a mammal in need thereof, as classified in class 424, subclasses 188.1 and 208.1.

1. Inventions I and II are related as a product and a method of making said product. The inventions can be shown to be distinct if either or both of the following can be shown that: (1) the method of making the product as claimed can be used to make a materially different product; or (2) the product as claimed can be made by another method that is materially different from the instantly claimed method of making said product. See MPEP § 806.05(f). In the instant case, a pharmaceutical composition in solid dosage form as claimed in Invention I can be made by another method that is materially different from the method claimed in Invention II. For example, as opposed to making a pharmaceutical composition in solid dosage form as claimed in Invention II, the pharmaceutical composition in solid dosage form claimed in Invention I, may alternatively be made by dry mixing together the components of said pharmaceutical composition to form a homogenous mixture, as

opposed to first preparing a homogeneous melt of said pharmaceutical composition then allowing said homogeneous melt to solidify into a solid dispersion, followed by milling and tableting said homogenous mixture.

Inventions I and III are related as a product and a method of using said product, respectively. The inventions can be shown to be distinct if either or both of the following can be shown that: (1) the method of using the product as claimed can be practiced with another materially different product; or (2) the product as claimed can be used by another method that is materially different from the instantly claimed method of using said product. See MPEP § 806.05(h). In the instant case, a pharmaceutical composition in solid dosage form as claimed in Invention I can be used by another method that is materially different from the method claimed in Invention III. For example, as opposed to a method of treating an HIV infection in a mammal as claimed in Invention III, the pharmaceutical composition in solid dosage form claimed in Invention I may alternatively be used to treat tuberculosis.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. See MPEP §§ 802.01 and 806.06. In the instant case, the method claimed in Invention III has a function and effect of treating an HIV infection in a mammal, whereas the method claimed in Invention II has a function and effect of preparing a pharmaceutical composition in solid dosage form. As a result, the method claimed in Invention III has a materially different function and effect from the method claimed in Invention II, and are therefore unrelated.

Because these inventions are independent and distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, the prior art search required for each respective invention would be divergent, thereby causing an undue search burden.

As a result, restriction for examination purposes as indicated is proper. Applicants are therefore required under 35 U.S.C. § 121 to elect a single invention for prosecution on the merits.

2. Claims 1, 3, 7-14, 19, 20 and 22 are generic to a plurality of disclosed patentably distinct species of HIV protease inhibitor. The disclosed species are patentably distinct, each from the other, because they possess different molecular structures, as well as different physicochemical properties. Therefore, restriction for examination purposes as indicated is proper.

Even though this requirement is traversed, Applicants are further required under 35 U.S.C. § 121 to elect, for search purposes only, a single disclosed patentably distinct species of either an HIV protease inhibitor (i.e., ritonavir), or a specific mixture of HIV protease inhibitors (i.e., a mixture of ritonavir and lopinavir), for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable. Currently, claims 1, 3, 7-14, 19 and 20 are generic. In addition to including a listing of all claims, as well as any claims subsequently added thereto, which are readable upon the elected species, Applicants should also include a chemical structure or a molecular formula of the elected compound, if a chemical structure or a molecular formula of said compound is not already contained within the instant specification. If Applicants are unable to provide the chemical structure or the molecular formula of said compound, the CAS (Chemical Abstract Service) number assigned to said compound will suffice.

3. Claims 1, 2, 7, 15-17, 20 and 22 are generic to a plurality of disclosed patentably distinct species of pharmaceutically acceptable water-soluble polymer. The disclosed species are patentably distinct, each from the other, because they possess different molecular structures, as well as different physicochemical properties. Therefore, restriction for examination purposes as indicated is proper.

Even though this requirement is traversed, Applicants are further required under 35 U.S.C. § 121 to elect, for search purposes only, a single disclosed patentably distinct species of pharmaceutically acceptable water-soluble polymer (i.e., an N-vinyl pyrrolidone homopolymer), for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable. Currently, claims 1, 2, 7, 15-17, 20 and 22 are generic. Applicants should also include a listing of all claims, in addition to any claims subsequently added thereto, which are readable upon the species that is elected consonant with this requirement.

4. Claims 1, 4-7, 20 and 22 are generic to a plurality of disclosed patentably distinct species of pharmaceutically acceptable surfactant. The disclosed species are patentably distinct, each from the other, because they possess different molecular structures, as well as different physicochemical properties. Therefore, restriction for examination purposes as indicated is proper.

Even though this requirement is traversed, Applicants are further required under 35 U.S.C. § 121 to elect, for search purposes only, a single disclosed patentably distinct species of pharmaceutically acceptable surfactant (i.e., sorbitan monolaurate (a.k.a. Span® 20)), for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable. Currently, claims 1, 4-7, 20 and 22 are generic. Applicants should also include a listing of all claims, in addition to any claims subsequently added thereto, which are readable upon the species that is elected consonant with this requirement.

Conclusion to Restriction Requirement

The Examiner has required restriction between product, methods of making, and methods of using claims. Where Applicants elect claims directed to a product, and the product claim is subsequently found allowable, withdrawn methods of making and methods of using claims that depend

from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Methods of making and methods of using claims that depend from or otherwise include all the limitations of the patentable product claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined methods of making and methods of using claims will be withdrawn, and the rejoined methods of making and methods of using claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §§ 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and methods of making and methods of using claims may be maintained. Withdrawn methods of making and methods of using claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicants are advised that the methods of making and methods of using claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

Applicants are advised that a fully responsive reply to this requirement must include an explicit identification of a single disclosed patentably distinct species of either an HIV protease inhibitor (i.e.,

ritonavir), or a specific mixture of HIV protease inhibitors (i.e., a mixture of ritonavir and lopinavir), as well as a single disclosed patentably distinct species of pharmaceutically acceptable water-soluble polymer (i.e., an N-vinyl pyrrolidone homopolymer) and pharmaceutically acceptable surfactant (i.e., sorbitan monolaurate (a.k.a. Span® 20)), that is elected consonant with this requirement, and a listing of all claims, including any claims subsequently added thereto, which are readable upon the elected species. An argument that a claim is allowable or that claims are not generic is considered nonresponsive unless accompanied by an explicit election of a specific species and subspecies. See 37 C.F.R. § 1.143.

Should Applicants traverse on the ground that the species are not patentably distinct, Applicants should submit evidence or identify such evidence now of record showing the species and subspecies to be obvious variants over one another or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other inventions.

If claims are added after the election, Applicants must explicitly indicate which claims are readable upon the elected species. See MPEP § 809.02(a). Amendments submitted after final rejection are governed by 37 CFR 1.116, whereas amendments submitted after allowance are governed by 37 CFR 1.312.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named Inventors is no longer an actual Inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

Due to the complex nature of the instant restriction requirement, a written restriction requirement was necessitated. See MPEP § 812.01.

Contact Information

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to David P. Stitzel, M.S., Esq., whose telephone number is 571-272-8508. The Examiner can normally be reached on Monday-Friday, from 7:30AM-6:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Johann Richter, Ph.D., Esq., can be reached at 571-272-0646. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see http://pair-direct.uspto.gov. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David P. Stitzel, M.S., Esq.
Patent Examiner
Technology Center 1600
Group Art Unit 1616

Johann Richter, Ph.D., Esq.
Supervisory Patent Examiner
Technology Center 1600
Group Art Unit 1616